K051245
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510(k) Summary

SUBMITTED FOR:

Company Name: **Proxy Biomedical, Ltd.**
Address: Coilleach, Spiddal
Galway, IRELAND
Caitriona Conneely, Quality Assurance Manager

Tel: 353 91 896900

Submitted by: Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
715-549-6035
715-549-5380

CONTACT PERSON: Elaine Duncan
DATE PREPARED: September 4, 2012 (revised)
TRADE NAME: Polyform™ Synthetic Mesh
COMMON NAME: Surgical Mesh
PROCODE OTO
CLASS/REGULATION: Class II/21 CFR878.3300
FDA REVIEW PANEL: Obstetrics/Gynecology

SUBSTANTIALLY EQUIVALENT TO: Polyform™ Synthetic Mesh is substantially equivalent to the Mersilene Mesh (Ethicon, Inc.), the Prolene Soft Mesh (Ethicon, Inc.), and the Bard Mesh (C.R. Bard, Inc.) a polypropylene mesh.

DESCRIPTION of the DEVICE:
Polyform™ Synthetic Mesh is intended to be utilized for surgical procedures pertaining to the pelvic floor. Polyform Synthetic Mesh is supplied sterile and provided in sheet form to be cut to size and sutured by the surgeon to meet the individual patient's needs. Polyform Synthetic Mesh is manufactured from monofilament polypropylene fibers.

INDICATIONS FOR USE:
Polyform™ Synthetic Mesh is indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor via an abdominal approach, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

SUMMARY of TESTING:
Bench test data reveal Polyform™ Synthetic Mesh has mechanical and material characterization values that are substantially equivalent to the predicate devices. The biocompatibility test results show that the material used in the design and manufacture of the device is non-toxic and non-sensitizing to biological tissues consistent with their intended use.Updated test data on the bench and the rodent, as summarized in the updated product brochure, shows comparable technical properties to the more contemporary material properties like those in the Gynemesh PS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

OCT 26 2012

Proxy BioMedical, Ltd.
% Elaine Duncan, M.S.M.E., RAC
President
Paladin Medical Incorporated
P.O. Box 560
STILLWATER MN 55082-0560

Re: K051245
Trade/Device Name: Polyform™ Synthetic Mesh
Regulation Number: 21 CFR § 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTO
Dated (Date on orig SE ltr): May 11, 2005
Received (Date on orig SE ltr) : May 16, 2012

Dear Ms. Duncan:

This letter corrects our substantially equivalent letter of June 17, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051245

Device Name: Polyform™ Synthetic Mesh

Indications for Use:

Polyform™ Synthetic Mesh is indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor via an abdominal approach, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K051245

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number _____